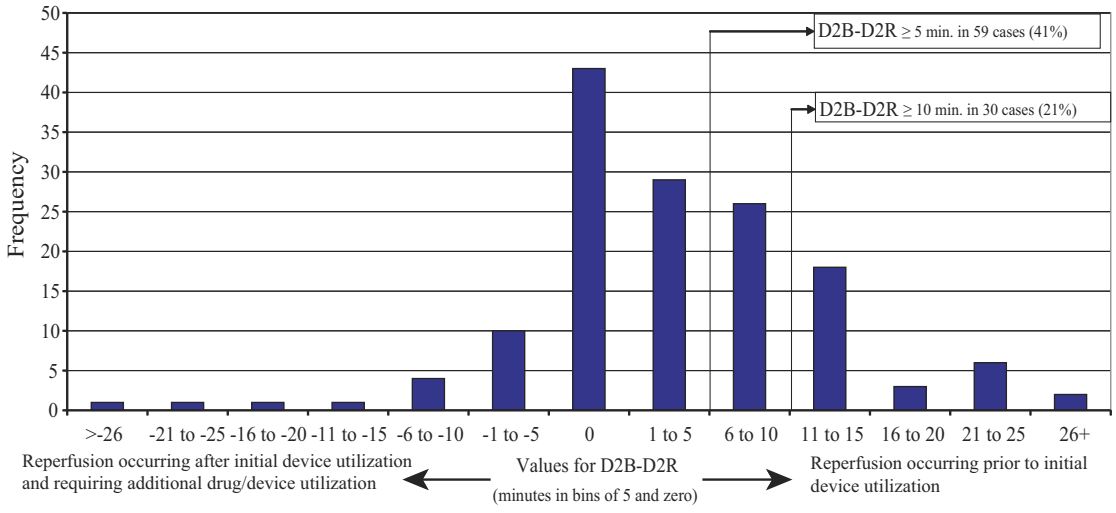

Figure 1 Frequency of Values for D2B Minus D2R (n = 145)

The difference between D2B and D2R for each case. D2B = door-to-balloon time; D2R = door-to-reperfusion time.

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Please note: Dr. Giugliano has served on the Speakers' Bureau of Schering Pharmaceuticals, Merck, Abbott, Pfizer, Radi/St. Jude Medical, Cordis, and AstraZeneca; has served as a consultant to Abbott, Cordis, Medtronic, and Gerson Lehrman Group; has received research support from Cordis, Medtronic, Novartis, and AstraZeneca; and has served on the advisory board of Siemens. Dr. Schweiger has received research support from Boston Scientific and served on the Speakers' Bureau for Sanofi-Aventis.

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Letters to the Editor

DIAL Trial Not Included in a Review of Health Failure Management Programs

Recently, Clark et al. (1) reviewed what they considered all available evidence on the effectiveness of disease management trials in heart failure, concluding that the evidence thus far lacks methodological quality. They particularly emphasized the poor quality of reports and design methods suggested by the Consolidated Standards of Reporting Trials statement.

We fully agree with the importance of following such rules, not only during the reporting and writing phase but also during the design and implementation of clinical trials.

For this reason, we were surprised by the omission of the DIAL (Randomized Trial of Telephone Intervention in Chronic Heart Failure) (2) from the investigators' discussion. DIAL was the

largest and among the best designed and implemented trials in this area. The trial tested the effectiveness of a very applicable telephone-based intervention, including more than 50 centers and 1,500 patients, which reduced heart failure admissions by 30% (3). In contrast, most trials in this area have included patients from single centers, in academic environments, implementing complex programs, and in general they have not obtained similar results. Furthermore, DIAL was designed and reported according to Consolidated Standards of Reporting Trials guidelines; its report in the *British Medical Journal* fulfilled all aspects required by the statement, including a clearly defined intervention, a comparator or intervention in control group, measurement of events, a clearly defined population, clear statements about the therapies and intensity of care in the control group, a flow chart of participants, and clearly stated objectives, end points, statistical analyses, and results.

DIAL was also an independent clinical trial and was conducted in Argentina. Although we believe that these characteristics could make DIAL's results less applicable for reviewers in developed countries, we would like to suggest that Clark et al. (1) discuss all available evidence on the topic to both avoid bias and help physicians make appropriate decisions about the appropriateness and effectiveness of disease management programs in heart failure.

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Reply

Dr. Ferrante and colleagues are correct to draw attention to the merits of the DIAL (Randomized Trial of Telephone Intervention in Chronic Heart Failure) because, unlike other trials, it was a large and comparatively well-described intervention delivered in a middle-income country. As such, DIAL is a welcome addition to the evidence base.

However, we disagree that reports of DIAL meet the requirements of the *modified* Consolidated Standards of Reporting Trials statement for nonpharmacological trials (1), because the original and companion reports (2) do not identify what usual care consisted of or how the care provided to the intervention group was standardized or monitored. These new standards are important, because they reflect principles of critical appraisal, and detailed information is necessary for rigorous systematic review (3).

We agree with the authors that the results of program trials are inconsistent. Current evidence does not adequately conceptualize or describe programs (3). However, it is *because* of these weaknesses that further meta-analysis of programs is inappropriate. As such, we did not seek to include "all" available evidence in our viewpoint but identified recent trials that did not find programs to be beneficial.

We drew attention to the lack of understanding of why program effects vary (4). These variations can be dismissed or attributed to biases or methodological weaknesses but may reflect actual differences in effects. Indeed, a very large recent trial (5) of another predominantly telephone-based program for patients (n = 30,000) with heart failure and diabetes reinforced the need to understand program effects better. This independent evaluation found no benefits from programs on hospitalization, mortality, patient satisfaction, self-care, or mental and physical functioning. Costs "far exceeded" savings. These negative results must be considered in the light of other positive findings, including those from DIAL.

In the face of these variations, proponents of different types of programs may continue to argue which type of program is "best," but this reflects an overly simplistic approach to evidence-based health services. Different types of programs are likely to be suitable for different settings and populations with different resources. Developing a more nuanced and context-responsive evidence base is now vital.

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